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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,403	09/01/2006	Nobuhiko Fushimi	Q96347	9581

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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

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02/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,403	FUSHIMI ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 25-29* is/are pending in the application.

4a) Of the above claim(s) *3,17-20 and 25-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2 and 4-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1.pg / 01Sep2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is the national stage entry of PCT/JP05/04152, filed 03 Mar 2005; and claims benefit of foreign priority document JAPAN 2004-61429, filed 04 Mar 2004; currently an English language translation of this foreign priority document has not been filed.

Claims 1-20 and 25-29 are pending in the current application. Claims 17-20 and 25-29, drawn to non-elected inventions, are withdrawn. Claim 3, drawn to non-elected species, are withdrawn. Claims 1, 2 and 4-16 are examined on the merits herein.

Election/Restrictions

Applicant's election of the invention of Group I, claims 1-16, in the reply filed on 15 Jan 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 17-20 and 25-29 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 Jan 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

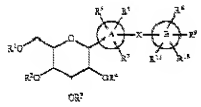
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 4-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imamura et al. (WIPO Publication WO2004/080990, published 23 Sep 2004, of record) in view of Shell (US Patent 5,582,837, issued 10 Dec 1996, cited in PTO-892). US Pre-Grant Publication US2006/0122126 (cited in PTO-892) is provided as an English-language equivalent of WIPO Publication WO2004/080990, and referred to as Imamura et al. herein.

Imamura et al. discloses a compound to treat diabetes of formula (I)

[1] C-glycoside derivatives of the following formula (I) and salts thereof.

[Chemical Formula]



wherein

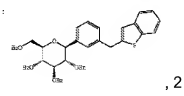
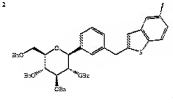
the A ring can represent an unsaturated eight to ten-membered bicyclic heteroaryl ring having 1 S (page 2, paragraph 14), specifically benzothiophene (page 3, paragraph 27),

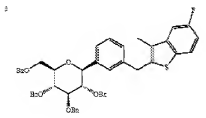
the X can represent a lower alkylene (page 2, paragraph 16), specifically methylene (page 3, paragraph 31),

the B ring can represent a benzene ring (page 2, paragraph 15),

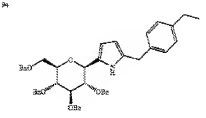
R^1-R^{10} can represent hydrogen (page 2, paragraph 18 and 19), and

R^{11} can represent a lower alkyl (page 2, paragraph 19), specifically methyl (page 3, paragraph 30).

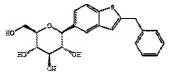
Imamura et al. discloses a variety of aryl C-glycosides, for example the compounds of examples 1  , 2  , 5



(page 31, table 7), 94

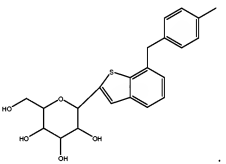


(page 50, table 22), and



(page 74, table 39, right column). Imamura et al. discloses the compound present in a solid composition for oral administration containing hydroxypropylcellulose and optionally coated with hydroxypropylcellulose.

Imamura et al. does not specifically disclose the compound 2-(β-D-glucospyranosyl)-7-(4-methylbenzyl)benzo[*b*]thiophene,



. Imamura et al. does not specifically disclose the compound in a sustained release formulation.

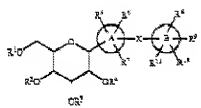
Shell teaches sustained-release oral drug dosage forms comprising the drug dispersed with alkyl-substituted cellulose (column 1, lines 58-62). Shell teaches sustained-release formulations reduce side effects of the drug and allows for treatment with less total amount of drug (column 2, lines 52-58).

It would have been one of ordinary skill in the art at the time of the invention to practice the invention of Imamura et al. using the specific compound 2-(β-D-

glucospyranosyl)-7-(4-methylbenzyl)benzo[*b*]thiophene in the form of a sustained release formulation. It would have been obvious to try, selecting from a finite number of predictable solutions to practice the generic formula disclosed by Imamura et al.,

[1] C-glycoside derivatives of the following formula (I) and salts thereof:

[Chemical Formula]

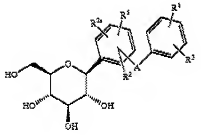


, with the specific compound 2-(β-D-glucospyranosyl)-7-(4-methylbenzyl)benzo[*b*]thiophene. Imamura et al. discloses examples of benzothiophenes with different patterns of substitution, examples 1, 2 and 5. Imamura et al. discloses a 4-alkylbenzyl group substituent of a heteroaryl C-glycoside, example 94. Imamura et al. discloses a C-glycoside of benzothiophene with a benzyl group substituent. This teaching of varying the identity and substitution patterns of the A and B ring disclosed by Imamura et al. would motivate one of ordinary skill in the art at the time of the invention to select from a finite number of predictable solutions to practice the generic formula disclosed by Imamura et al. with the specific compound 2-(β-D-glucospyranosyl)-7-(4-methylbenzyl)benzo[*b*]thiophene. It would have been obvious to one of ordinary skill in the art at the time of the invention to improve the compound in a solid composition for oral administration containing hydroxypropylcellulose disclosed by Imamura et al. using the known method of sustained-release formulations. Shell teaches that sustained-release formulations

reduce side effects of the drug and allows for treatment with less total amount of drug. One of ordinary skill in the art at the time of the invention would have a reasonable expectation of success to combine the teachings of Shell with the compound in a solid composition for oral administration containing hydroxypropylcellulose disclosed by Imamura et al. because the composition disclosed by Imamura et al. contains an alkyl-substituted cellulose.

Claims 1-2 and 4-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellsworth et al. (US Patent 6,414,126, issued 02 Jul 2002, cited in PTO-892) in view of Bedell et al. (J. Org. Chem., 1962, 27, p2026-2031, cited in PTO-892) and further in view of Shell (US Patent 5,582,837, issued 10 Dec 1996, cited in PTO-892).

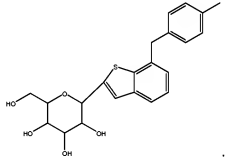
Ellsworth et al. discloses a C-aryl glycoside compound having the structure



wherein

R^1, R^2 and R^{2a} can respresent hydrogen or two of R^1, R^2 and R^{2a} together with the carbons to which they are attached can form an annelated five, six or seven membered carbocycle or heterocycle which may contain 1 to 4 heteroatoms in the ring which are N, O, S, SO, and/or SO_2 (column 6, lines 25-45), R^3 and R^4 are hydrogen and alkyl (column 6, lines 46-47) and A is $(CH_2)_n$ whwere n is 0-3 (column 7, line 1). Ellsworth et al. defines the term alkyl to specifically include methyl (column 22, line 53). Ellsworth et

al. defines the term aryl to specifically include benzothiophene,  (column 25, line 45). The compounds disclosed by Ellsworth et al. possess activity as inhibitors of sodium dependent glucose transports and are useful in the treatment of diabetes and complications of diabetes (column 7, lines 22-27). Ellsworth et al. discloses example 16 wherein the C-aryl glycoside is substituted with a 4-methylbenzyl group (column 64, line 34). Ellsworth et al. discloses related compounds containing a benzothiophene (spanning column 3, lines 66-67 and column 4, lines 1-2). Ellsworth et al. discloses the compound administered as a pharmaceutical composition formulated in an oral dosage form (column 35, lines 29-46), with the dose administered, dose form and regiment adjusted to achieve the desired result (column 33, lines 41-44).

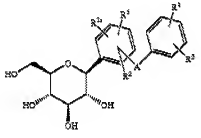
Ellsworth et al. does not specifically disclose the compound 2-(β-D-glucospyranosyl)-7-(4-methylbenzyl)benzo[*b*]thiophene,  . Ellsworth et al. does not specifically disclose the pharmaceutical composition in the form of a sustained release formulation.

Bedell et al. teaches that formation of a C-C bond to benzo[*b*]thiophene occurs predominantly at the 2- position (page 2027, right column, lines 33-36).

Shell teaches sustained-release oral drug dosage forms comprising the drug dispersed with alkyl-substituted cellulose (column 1, lines 58-62). Shell teaches

sustained-release formulations reduce side effects of the drug and allows for treatment with less total amount of drug (column 2, lines 52-58).

It would have been one of ordinary skill in the art at the time of the invention to practice the invention of Ellsworth et al. using the specific compound 2-(β-D-glucospyranosyl)-7-(4-methylbenzyl)benzo[*b*]thiophene in the form of a sustained release formulation. It would have been obvious to try, selecting from a finite number of predictable solutions to practice the generic formula disclosed by Ellsworth et al.,



, with the specific compound 2-(β-D-glucospyranosyl)-7-(4-methylbenzyl)benzo[*b*]thiophene. Ellsworth et al. discloses the example of a related compound containing benzothiophenes (spanning column 3, lines 66-67 and column 4, lines 1-2). Ellsworth et al. discloses a 4-methylbenzyl group substituent of a C-aryl glycoside, example 16. Ellsworth et al. discloses a C-aryl glycoside and defines aryl to include benzothiophene,  (column 25, line 45). This teaching of varying the identity and substitution patterns of the aryl rings disclosed by Ellsworth et al. would motivate one of ordinary skill in the art at the time of the invention to select from a finite number of predictable solutions to practice the generic formula disclosed by Ellsworth et al. with the specific compound 2-(β-D-glucospyranosyl)-7-(4-methylbenzyl)benzo[*b*]thiophene. One of ordinary skill in the art at the time of the

invention would be motivated to generate the C-C bond of the C-glycoside 2-(β-D-glucospyranosyl) benzo[*b*]thiophene because of the teaching of Bedell et al. that formation of a C-C bond to benzo[*b*]thiophene occurs predominantly at the 2- position. It would have been obvious to one of ordinary skill in the art at the time of the invention to improve the pharmaceutical composition disclosed by Ellsworth et al. according to the known method of sustained-release formulations taught by Shell. Shell teaches that sustained-release formulations reduce side effects of the drug and allows for treatment with less total amount of drug. One of ordinary skill in the art at the time of the invention would have a reasonable expectation of success to combine the teachings of sustained release formulations of Shell with the pharmaceutical composition disclosed by Ellsworth et al. because Ellsworth et al. discloses the pharmaceutical composition may be formulated employing conventional vehicles, diluents and additives (column 35, lines 34-37).

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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